Title 22. Social Security
Division 4. Environmental Health
Chapter 19. Certification of Environmental Laboratories

Article 1. Definitions

§64801.0114. Acceptable Results.

"Acceptable Results" means proficiency testing (PT) study data generated by a laboratory and in compliance with Section 64809 through 64809.030.

§64801.0116. Accredited College or University.

"Accredited College or University" means an educational facility which has met the standards of the United States of America Accrediting Commission for Senior Colleges and Universities or the Accrediting Commission for Community and Junior Colleges; or, if a non-United States college or university, one that is evaluated and found equivalent by the American Association of Collegiate Registrars and Admissions Officers.

§64801.0131. Agent.

"Agent", means the person who has been designated in writing (effective upon receipt by the Department) by the owner(s) of the laboratory to act in its behalf with the capacity that does not involve the operations of the laboratory and its staff, and that is for purposes of complying with this chapter or the statutes under which this chapter has been adopted. Even if the owner designates another person to act on his or her behalf, the owner shall remain fully responsible for ensuring compliance under this act.

§64801.0150. Alternate Test Procedure.

"Alternate Test Procedure" means an analytical test method, or procedure that is different in technic from the method(s) cited in Section 64811(b), and generates comparable results with accuracy, precision, and level of detection that are equivalent or better.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862.-

§64801.0157. Analyst.

"Analyst" means a person who performs analysis of environmental samples using an analytical method, reviews the data, determines if a sample requires repeat analysis, prepares reports, and other similar duties, and reports directly to the supervisor or the director.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.0170. Assistant.

"Assistant" means a person who assists the technician and/or analyst in carrying out the analysis of samples by an analytical method, and reports directly to the technician and/or analyst. The assistant's responsibilities are limited to preparation of reagents, calibration of pipetters, washing glassware, and other duties described in Section 64817.050.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.0184. Auxiliary Laboratory.

"Auxiliary Laboratory" means any stationary place:

(a) operated by the owner of a laboratory for the purpose of providing additional capacity, or to reduce or eliminate sample contamination; and

(b) where analyses in one or more of the same Field(s) of Testing as the laboratory to which it is auxiliary is performed; and

(c) under the supervision of the same director as the laboratory to which it is auxiliary; and

(d) that only receives samples from, and reports raw analytical data to, the laboratory to which it is auxiliary for its generation of the final report; and

(e) located at contiguous buildings on the same site and the transport of samples to the auxiliary laboratory is within a few minutes, and does not affect the quality of the analytical results.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.0350. Complete Application.

A "Complete Application" means a verified application for certification containing all the information required in Section 64803(a), utilizing ELAP form 001, rev 01, submittal of all applicable fees. and any other relevant information as may be required by the Department.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.0352. Confidential Business Information.

"Confidential Business Information" means any information or documents maintained by a laboratory in the ordinary course of business that, if made public, would compromise the laboratory.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.0413. Deficiency.

"Deficiency" means not in compliance with certification requirements.

§64801.0410. Days.

"Days" means calendar days, unless otherwise indicated.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.0428. Director.

"Director" means the laboratory staff person who is approved by the Department to direct a laboratory under this chapter and who is responsible for the overall operation and administration of the laboratory, including the day-to-day supervision of all personnel, all laboratory activities

including technical, analytical and operational laboratory activities, and is responsible for data reporting operations, including quality of reported data, in the laboratory.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.0552. ELAP.

"ELAP" means the Environmental Laboratory Accreditation Program.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.0622. Field of Accreditation or FoA.

"Field of Accreditation" or "FoA" means Field of Testing.

§64801.0642. Field of Testing.

"Field of Testing" means the testing category identified in Sections 100860.1 and 100862 of the Health and Safety Code. Each testing category represents the collected sample type by matrix and testing type by discipline.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.0626. Finding.

A "finding" means any laboratory practice, performance, or skill that is determined by the Department during an on-site inspection to be technically inappropriate for use, in violation of statute or regulation, a deviation from a standard practice or analytical method, or a lack thereof.

§64801.0765. Group-of-Analytes.

"Group-of-Analytes" means some or all of the organic chemicals, radionuclides, or micro-organisms that can be analyzed by a single analytical method for which a laboratory is seeking certification.

§64801.0955. Inspection Report.

"Inspection Report" means a report issued by the Department to a laboratory which includes the results from an on-site inspection.

§64801.0957. Interim Certificate.

"Interim certificate" means a temporary certificate issued in compliance with section 64803.030.

§64801.1210. Laboratory

"Laboratory" means any stationary building(s) or mobile laboratory where the analyses in any of the Field(s) of Testing listed in Section 100860.1 or Section 100862 of the Heath and Safety Code are performed, and meets the requirements of Sections 64813 and 64815.010.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.1315. Method.

"Method" means an analytical process or procedure for use in the determination of the presence/absence and/or quantitation of a pollutant or contaminant in an environmental sample.

§**64801.1360. Mobile Laboratory.**

"Mobile Laboratory" means a vehicle, vessel, aircraft, or trailer where, analyses in the Field(s) of Testing in Section 100860.1 or 100862 of the Health and Safety Code are performed.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.1590. Owner.

"Owner" means any person with an ownership or control interest in a laboratory regulated under article 3 of the Health and Safety Code and the regulations adopted thereunder. "Person" with an ownership or control interest" means a person, partnership, or corporation that has an ownership interest totaling 5% or more in the environmental laboratory; (As used in this section, "ownership interest" means the possession of equity in capital, stock, or profits.)

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.1620. Performance Based Method.

"Performance Based Method" means a modified method from one that was initially approved by a government entity, and the modified method is not an alternate test procedure.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.1622. Performance Evaluation Process.

"Performance Evaluation Process" means the process of evaluating laboratory performance through the use of proficiency testing studies as described in Section 64809.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.1630. Physical Property.

"Physical Property" means a measurement of the physical characteristics of an environmental sample.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.1680. Proficiency Testing Study.

"Proficiency Testing Study" means a uniform examination process by which a laboratory's performance in analysis of samples that are representative of real world samples is determined.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.1790. Quality Assurance Officer.

"Quality Assurance Officer" means a person who monitors the quality of the data generated, and reports problems with the quality of the data directly to the director and the owner(s) of the laboratory.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.1816. Real World Samples.

"Real World Samples" means samples that are collected from the environment, and are received at an environmental testing laboratory for analysis to meet regulatory requirements. Such samples are not quality control samples, proficiency testing study samples, or artificially prepared samples.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.1818. Reference Laboratory Data.

"Reference Laboratory Data" means data generated by a laboratory that is owned and operated by the State or federal government that utilizes Federal or State approved methods and is capable of conducting unusual, highly specialized, complex analyses, as well as routine environmental testing of samples for regulatory purposes.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.1820. Representative Analytes.

"Representative Analytes" means various analytes selected by the State or Federal agency to represent analysis by a particular method in a proficiency testing study.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.1950. Sophisticated Laboratory Instruments.

"Sophisticated Laboratory Instruments" means analytical instrumentation such as gas chromatography/mass spectrometers (GC/MS), inductively coupled plasma spectrometers (ICP), direct current plasma spectrometers (ICP-MS), liquid chromatography/mass spectrometers (LC-MS), atomic absorption spectrophotometers (AA), gas chromatographs (GC), alpha particle or gamma ray spectrophotometer, electron microscopes (EM), polarized light microscope (PLM), high pressure liquid chromatographs (HPLC), or other similar instruments including aquatic organisms in toxicity testing of wastewater and hazardous waste.

§64801.1960. Definition of State Monitored Analyte, Group-of-Analytes, or Physical Property.

"State Monitored Analyte, Group-of-Analytes, or Physical Property" means the analyte, group-of-analytes, or physical property is not Federal regulated or monitored, and is only monitored by the State.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.1962. Stationary Building.

"Stationary Building" means a laboratory that is permanent and non-movable and may include fixed-in-place vehicles.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.1990. Supervisor.

"Supervisor" means a person who supervises the work performed in a laboratory, or the users of, and/or performs analyses himself/herself with the sophisticated laboratory instrument(s) or other instrument/equipment.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.2020. Technician.

"Technician" means a person who performs analysis of environmental samples using analytical methods, and reports directly to the Analyst or supervisor.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.2064. Trade Secrets.

"Trade Secrets" may include, but are not limited to, any formula, plan, pattern, process, tool, mechanism, compound, procedure, production data, or compilation of information which is not patented, which is known only to certain individuals within a commercial concern who are using it to fabricate, produce, or compound an article of trade or a service having commercial value and which gives its user an opportunity to obtain a business advantage over competitors who do not know or use it.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code; Section 6254.7(d), Government Code.

§64801.2066. Trailer.

"Trailer" means a vehicle designed for carrying persons or property on its own structure and for being drawn by a motor vehicle and so constructed that no part of its weight rests upon any other vehicle.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code; Section 630, Vehicle Code.

§64801.2068. True Value.

"True Value" means the gravimetric true concentration of an analyte, or a reference value obtained from a primary standard for the analyte, in a proficiency testing study sample.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.2184. Utility-Owned.

"Utility-Owned" means laboratories owned and operated by federal, state, city, or county agencies.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.2220. Vehicle.

"Vehicle" means a device by which any person or property may be propelled, moved, or drawn upon a highway, excepting a device moved exclusively by human power or used exclusively upon stationary rails or track.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code; Section 670, Vehicle Code.

§64801.2284. Verified Application.

"Verified Application" means that the truth and accuracy of the information in the application has been attested to by the signature of a laboratory Owner, or his/her agent.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.2288. Vessel.

"Vessel" includes ships of all kinds, steamboats, steamships, canal boats, barges, sailing vessels, and every structure adapted to be navigated from place to place for the transportation of merchandise or persons.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code; Section 21, Harbors and Navigation Code.

Article 2. Accreditation Process.

§64803. Basic Accreditation Requirements.

(a) To obtain a certificate for the duration of 24 months, a laboratory shall meet the following requirements:

(1) submit a complete application pursuant to Section 64805;

(2) complete the on-site inspection process, unless otherwise stated in Sections 64803.010 through 64803.060;

(3) participate in the appropriate proficiency testing study and receive acceptable results pursuant to Section 64809;

(4) make payment of the appropriate fees pursuant to Section 64806, or as described in Sections 64803.010 through 64803.060

§64803.010. Accreditation Process for Initial Certification.

(a) A laboratory and its auxiliary laboratories shall be certified for the Field of Testing identified on the application for initial certification when all the following have occurred:

(1) a complete application has been filed with the Department pursuant to Section 64805; and

(2) an onsite inspection pursuant to Section 64807 has occurred and a response to any cited deficiencies has been received and accepted by the Department; and

(3) acceptable results for proficiency testing sample study sets have been received by the Department pursuant to Section 64809; and

(4) payment of the basic fee and per-Field-of-Testing fees published by the Department pursuant to Section 64806 has been made to the Department.

(b) The Department's estimated schedule for processing a complete application for initial certification from the receipt of the complete application to the final decision regarding issuance or denial of a certificate is as follows:

(1) the median time is 90 days;

(2) the minimum time is 30 days;

(3) the maximum time is 180 days.

Note: Authority cited: Sections ~~208, 1011 and 1012~~***100275 and 100830***, Health and Safety Code; and Section 15376, Government Code. Reference: Section 15376, Government Code; and Sections ~~113, 1012, 1013, 1014 and 1015~~***100425, 100830, 100840, 100845, 100850, and 100860.1***, Health and Safety Code.

§64803.020. Accreditation Process for Amendment to Certification.

(a) A laboratory seeking to amend its certificate shall file an amendment application detailing the changes to the certificate. All requested changes shall be made and an updated certificate issued when all of the following have occurred:

(1) a complete application has been filed with the Department pursuant to Section 64805; and

(2) a site inspection pursuant to Section 64807 has occurred and a response to any cited deficiencies has been received and accepted by the Department, if the amendment applies to the addition of a Field of Testing to the certificate; and

(3) acceptable results for proficiency testing study samples have been received by the Department pursuant to Section 64809; and

(4) payment for a per-Field-of-Testing fee published by the Department pursuant to Section 64806 for each Field of Testing to be amended or added to the certificate has been made to the Department.

(b) If the amendment application in section (a) applies to the addition within a Field of Testing that appears on the laboratory's current certificate and the Department had performed the on-site inspection of the laboratory for that Field of Testing for the same method of analysis within the past 12 months and the laboratory had successfully completed the on-site process, then an onsite inspection for that particular method of analysis in the Field of Testing is not required. The laboratory shall provide any additional information or documentations regarding the amendment upon request by the Department within 30 days. Inaction by the laboratory to

provide the requested information or documentation within the 30-day time period will be deemed abandonment by the laboratory of the application.

(c) If the amendment application applies to Section 64803.020(b), then the laboratory shall pay the fee that appears in Section 64806.010 per Field of Testing amended.

(d) If the amendment application involves changes to personnel, laboratory name, address, or other administrative function not part of any Field of Testing listed in section 100860.1 of the Health and Safety Code, then the laboratory shall pay the fee that appears in Section 64806.010. If the amendment application involves dropping or withdrawal of testing parameters listed as certified, then the laboratory shall pay the applicable fee that appears in Section 64806.010 per application.

(e) If the amendment application involves personnel turnover of less than 50% of the previous staff, then an on-site inspection is not required.

(f) The laboratory shall report all personnel changes to the Department, in writing, within 30 days.

(g) Laboratories seeking an amendment to add a Field(s) of Testing or increase the certified testing parameters within a Field of Testing in its current certificate shall not perform analyses in the additional Field(s) of Testing, or additional testing parameters within a Field of Testing, until approved by the Department as evidenced by the issuance of an amended certificate.

(h) Laboratories seeking removal of a Field(s) of Testing or of certified testing parameters within a Field of Testing in its current certificate shall not perform analyses in the Field of Testing, or certified testing parameters requested for removal within an existing Field of Testing, after the date of its written request for removal.

(i) For amendment of certification, the estimated schedule for processing a complete application from the receipt of the application to the final decision regarding issuance or denial of an amended certificate is as follows:

(1) the median time is 60 days;

(2) the minimum time is 30 days;

(3) the maximum time is 120 days.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code; and Section 15376, Government Code. Reference: Section 15376, Government Code; and Sections 100425, 100830, 100840, 100845, 100847, 100850, 100851, and 100860.1, Health and Safety Code.

§64803.030. Accreditation Process for Interim Certification.

(a) A laboratory seeking interim certification under authority of Health and Safety Code, Section 100850(d), may submit a written request, with or after submittal of an application or during the laboratory's certification, for an interim certificate for a specific analyte, group-of-analytes, physical property, method of analysis, or Fields of Testing.

(b) An interim certificate shall be issued when the following have occurred:

(1) the laboratory has submitted a complete application;

(2) acceptable results for applicable proficiency testing study samples have been received by the Department pursuant to Section 64809 (if available for the analytes, group-of-analytes, physical properties, methods, or Field of Testing);

(3) payment of the basic and per Field-of-Testing fee published by the Department pursuant to Section 64806 for each Field of Testing has been received by the Department;

(4) completion of the requirements of Section 64815.010 for initial demonstration of capability, method detection limits, data packages, and standard operating procedures;

(b) An interim certificate for a microbiology method will not be issued by the Department, unless the laboratory is already accredited for the same method for use in analysis of a similar matrix.

(c) For interim certification, the estimated schedule for processing a complete application from the receipt of the application to the final decision regarding issuance or denial of an interim certificate is as follows:

(1) the median time is 60 days;

(2) the minimum time is 30 days;

(3) the maximum time is 120 days.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code; and Section 15376, Government Code. Reference: Section 15376, Government Code; and Sections 100425, 100830, 100840, 100845, 100847, 100850, 100851, and 100860.1, Health and Safety Code.

§64803.040. Accreditation Process for Renewal of Certification.

(a) A laboratory and its auxiliary laboratory shall be certified for another 24-month period in the Field(s) of Testing that appear in the laboratory's current certificate when the following have occurred:

(1) a complete application for renewal has been filed with the Department pursuant to Section 64803; and

(2) the application was submitted before the expiration of the laboratory's certificate; and

(3) acceptable results for proficiency testing study sets have been received by the Department pursuant to Section 64809; and

(4) payment of the basic fee and per Field of Testing fee has been received by the Department.

(b) The certificate for a laboratory shall remain in effect until otherwise indicated upon the completion of the on-site inspection process described in Section 64807.010.

(c) For renewal of certification, the estimated schedule for processing a complete application from the receipt of the application to issuance of a certificate is a maximum of 30 days. The estimated schedule for completion of the on-site inspection process to the final decision regarding issuance of an updated certificate, or revocation of the certificate is as follows:

(1) the median time is 90 days;

(2) the minimum time is 60 days;

(3) the maximum time is 180 days.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code; and Section 15376, Government Code. Reference: Section 15376, Government Code; and Sections 100425, 100830, 100840, 100845, 100850, and 100860.1, Health and Safety Code.

§64803.050. Accreditation Process for Reinstatement after Revocation or Denial of a Certificate.

(a) When considering the denial or revocation of a certificate under Health and Safety Code Sections 100850, 100880, 100885, 100895, 100905, or 100907 for which application has been submitted under Health and Safety Code Section 100840, the Department, in evaluating the rehabilitation of the applicant and his/her present eligibility for a certificate, shall consider the following criteria:

(1) The nature and severity of the act(s) or crime(s) under consideration as grounds for denial;

(2) Evidence of any act(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial which also could be considered as grounds for denial under Section 100880 of the Health and Safety Code;

(3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subsection (a)(1) or (a)(2), but in no event will reinstatement occur sooner than 6 months after the date of revocation or denial;

(4) The extent to which the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed upon the applicant;

(5) Evidence, if any, of rehabilitation submitted by the applicant.

(b) The laboratory shall comply with the requirements that appear in Sections 64803.010 for initial certification, and 64806.020 for reinstatement application fees.

(c) An on-site inspection by the Department shall be performed on the laboratory as described in Section 64807.040.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code; and Section 15376, Government Code. Reference: Section 15376, Government Code; and Sections 100425, 100830, 100840, 100845, 100850, and 100860.1, Health and Safety Code.

§64803.060. Accreditation Process for Reinstatement of Certification after Suspension of a certificate.

(a) A laboratory that has its certificate suspended in whole or in part may apply for reinstatement of its certification status provided the laboratory has submitted a request for reinstatement.

(b) The laboratory shall be in compliance with Section 64806.020 for reinstatement application fees.

(c) The laboratory shall be found to be substantially in compliance with Article 3 of the Health and Safety Code and these regulations following an on-site inspection described in Section 64807.030.

Note: Authority cited: Sections 100275 and 100830, Health and Safety Code; and Section 15376, Government Code. Reference: Section 15376, Government Code; and Sections 100425, 100830, 100840, 100845, 100850, and 100860.1, Health and Safety Code.

Article 3. Application Process

§64805. Application.

(a) All laboratories seeking certification in any Field of Testing as listed in Health and Safety Code, Section 100860.1 shall submit a complete application utilizing ELAP form 001, rev 01**.** that includes the name or names of the owner or the owners, the names of the laboratory director or directors, the name and location of the laboratory and any other relevant information as may be required by the Department. Failure to respond to the Department's request for additional information necessary to determine compliance within thirty days from the date of receipt of the Department's request shall cause the application or renewal notice to be considered abandoned.

(b) An application for renewal of a certificate shall be received by the Department prior to the expiration date of the certificate or it shall expire by operation of law on the stated expiration date as specified in Health and Safety Code Section 100845~~1014~~(a).

Note: Authority cited: Sections ~~208 and 1011~~***100275 and 100850***, Health and Safety Code. Reference: Sections ~~1013, 1014 and 1017(e)~~***100840 and 100845***, Health and Safety Code.

§64806. Certification Fees.

(a) The following schedule of fees shall apply to every environmental laboratory applying for an initial, amendment, or renewal of Environmental Laboratory Accreditation Program certification:

(1) A non-refundable base or administrative fee of $1003 payable at the time of initial and renewal application for certification and annually thereafter, and

(2) An additional fee of $452 for each Field of Testing specified in Health and Safety Code Section 100860.1 which the laboratory has requested in its application, payable at the time of application for an initial, amended, or renewed ELAP certification, and annually thereafter.

Note: Authority cited: Sections ***100425,*** 100830, 100835(a) and 100860.1, Health and Safety Code. Reference: Section 100825, Health and Safety Code.

§64806.010. Amendment Application Fees.

(a) If the amendment application only applies to Section 64803.020(b), then the laboratory shall pay $250 per Field of Testing amended.

(b) If the amendment application only involves changes to personnel, laboratory name, address, or other administrative function not part of any Field of Testing listed in section 100860.1 of the Health and Safety Code, then the laboratory shall pay $25 per application.

(c) If the amendment application only involves dropping or withdrawal of testing parameters listed as certified, then the laboratory shall pay $25 per application.

Note: Authority cited: Sections 100425, 100830 and 100860.1, Health and Safety Code. Reference: Section 100825, Health and Safety Code.

§64806.020. Reinstatement Application Fees.

(a) If the laboratory submits a reinstatement application after revocation of its whole certificate, then the laboratory shall pay the fee as stated in Section 64806.

(b) If the laboratory submits a reinstatement application after revocation of part of its certificate, then the laboratory shall pay the fee for each affected Field of Testing as stated in Section 64806.

(c) If the laboratory submits a reinstatement application after suspension in whole or in part of its certificate, then the laboratory shall pay the fee for each affected Field of Testing as stated in Section 64806.

(d) If numerous on-site inspections are necessary to monitor compliance for reinstatement, then the laboratory shall pay an additional fee for each affected Field of Testing as stated in Section 64806 for each on-site inspection.

Note: Authority cited: Sections 100425, 100830 and 100860.1, Health and Safety Code. Reference: Section 100825, Health and Safety Code.

§64806.030. Other Fees.

(a) If a laboratory holding a certificate of NELAP accreditation submits an application for certification in the Fields of Testing that appear in Section 100860.1 of the Health and Safety

Code, then the laboratory shall pay the Field of Testing fee as described in Section 64806, and shall be exempt from the base fee that appears in Section 64806.

(b) A laboratory that submits an application for alternate test procedures (ATP) shall pay an initial fee in the amount of $250 for each ATP and each additional group-of-analytes or each particular analyte or physical property or each species if involving aquatic bioassay procedures. If the ATP requires additional review by a California State agency laboratory, then the applicant laboratory shall pay an additional fee in the amount of $1000 for each ATP. If proficiency testing samples specific for the requested group-of-analytes or particular analyte or physical property or each species (if involving aquatic bioassay procedures) are not readily available, then the laboratory shall pay for the cost of the proficiency testing sample that may be made available through the Department.

(c) A laboratory that submits an application for method modifications, which is not an ATP, shall pay a fee in the amount of $250 for each method modification and for each group-of-analytes or each particular analyte or physical property or each species if involving aquatic bioassay procedures. If the method modification requires additional review by a California State laboratory, then the applicant laboratory shall pay an additional fee in the amount of $1000 for each modification. If proficiency testing samples specific for the requested group-of-analytes or each particular analyte or physical property or each species (if involving aquatic bioassay procedures) are not readily available, then the laboratory shall pay for the cost of the proficiency testing sample that may be available through the Department .

(d) If a laboratory has undergone a sale or transfer of ownership, the laboratory shall pay a fee in the amount of $250.

Note: Authority cited: Sections 100425, 100830 and 100860.1, Health and Safety Code. Reference: Section 100825, Health and Safety Code.

§64806.080. Fines for Late Applications, Annual Payments, & Reports.

(a) When a laboratory submits a renewal application after the expiration date of its certificate and no later than 30 days after the expiration date, the laboratory shall pay a fine in the amount of $250 in addition to the application fee.

(b) When a laboratory fails to submit its annual payment for certification within 30 days after the 12-month certification period, the laboratory shall pay a fine in the amount of $250 in addition to its annual fee specified in Section 64806 to the Department.

(c) When a laboratory does not submit its statement of corrective actions by the date specified in the inspection report, the laboratory shall be cited and shall pay a fine in the amount of $250 per violation.

Note: Authority cited: Sections 100880 and 100860.1, Health and Safety Code. Reference: Section 100825, Health and Safety Code.

§64806.100. Fines for Findings from an On-site Inspection.

A laboratory cited for deficiencies from an on-site inspection may be fined for each deficiency up to the amount specified in Section 100880 of the Health and Safety Code.

Note: Authority cited: Sections 100880, Health and Safety Code. Reference: Section 100825, Health and Safety Code.

Article 4. On-site Inspections.

§64807. On-site Inspections for Initial and Amendment of Certification.

(a) On-site inspections shall be conducted by the Department after receipt of a laboratory application for initial or amendment of certification. During the on-site inspection, the Department shall verify the following:

(1) the laboratory uses only the analytical methods identified in Section 64811 and 64811.0100 for a Field of Testing for which the laboratory is seeking certification;

(2) the laboratory's instrumentation and equipment meet the requirements of Section 64813;

(3) the laboratory's quality assurance and quality control procedures meet the requirements of Section 64815 and 64815.010; and

(4) the laboratory data packets as described in Section 64815.010; and

(5) the laboratory standard operating procedures; and

(6) the laboratory training protocols which includes data, qualifications, and similar records and supporting documentations; and the laboratory staff, including the director, are qualified to perform the duties assigned to them; and

(7) the laboratory analyses of proficiency testing study samples; and

(8) the information contained in the application.

(b) Within 30 days of completion of an on-site inspection, the Department shall notify a laboratory, in writing, of its deficiencies, if any, in complying with the requirements of (a)(1) through (a)(8) above. No laboratory shall be issued a certificate in any Field of Testing applied for initial certification or amendment of its certificate unless it has corrected all deficiencies noted, has provided to the Department a statement, in writing of all corrective actions taken, and the Department has determined that the laboratory is operating in compliance with Article 3 of the Health and Safety Code and the regulations adopted thereunder.

(c) An on-site inspection shall be conducted within 60 days from the date of receipt by the Department of a laboratory's application. If an on-site inspection is not conducted within this time period and the delay is not a result of Department error or procedure, certification shall be denied pursuant to Section 64803(a).

(d) If the Department determines that the on-site inspection of a laboratory is to be delayed through no fault of the laboratory, then the laboratory may request for an interim certificate in accordance to Section 64803.030.

(e) The statement of corrective actions performed by a laboratory shall include details of its investigation of the deficiencies, the initiated corrections, the completed and any planned corrections, and implementation of processes for prevention or minimization of re-occurrence of the deficiencies. The time frame for submittal of such statement shall be 30 days, not to exceed 120 days.

(f) If a laboratory needs more than 30 days to prepare its statement of corrective actions, the laboratory shall submit to the Department a written request for an extension, prior to the deadline established in the "Notice of Deficiencies." The Department shall respond to the laboratory within 14 days of receipt of the request for extension. The extension period shall not exceed 90 days.

(g) If the statement of corrective actions does not adequately address the deficiencies, the laboratory shall be notified by the Department and given a final 30 days to submit an amended statement of corrective actions. If after the final 30 days the Department determines that the

submitted statement still does not adequately address the deficiencies, the laboratory shall be denied a certificate for the Fields of Testing affected.

Note: Authority cited: Sections ~~208,~~ ~~1011 and~~ ~~1012~~***100275, 100865 and 100880***, Health and Safety Code. Reference: Sections ***100850, 100865 and 100880***~~1015, 1018 and 1021~~, Health and Safety Code.

§64807.010. On-site Inspection for Renewal of Certification.

(a) An on-site inspection shall be conducted by the Department after receipt of a complete application for renewal of certification. During the on-site inspection, the Department shall verify the following:

(1) the laboratory uses only the analytical methods identified in Sections 64811 and 64811.0100 for a Field of Testing for which the laboratory is certified;

(2) the laboratory instrumentation and equipment meet the requirements of Section 64813;

(3) the changes to the laboratory quality assurance and quality control procedures meet the requirements of Sections 64815 and 64815.010 and are maintained; and

(4) the changes to its standard operating procedures; and

(6) the changes to training protocols, which includes data, qualifications, and similar records and supporting documentations; and the new or reassigned laboratory staff are qualified to perform the duties assigned to them; and

(7) the laboratory analyses of proficiency testing study samples; and

(8) the information contained in the application.

(b) If the laboratory upon renewal of its certificate is cited for deficiencies, the laboratory shall be subject to fines as described in Section 64806.100. The laboratory shall be subject to Section 64806.080 for late submittal of its statement of corrective actions. The laboratory shall be required to comply with Sections 64807(e) and 64807(f).

(c) If the laboratory had not corrected all deficiencies noted from the on-site inspection within the time frame established in the ELAP inspection report, then the laboratory shall be subject to citation(s) as specified in Health and Safety Code Section 100890 or 100895, and to revocation of its certificate in its entirety or parts thereof as authorized in Health and Safety Code Section 100905.

(d) If the laboratory statement of corrective actions does not adequately address the deficiencies, the process described in Section 64807(g) applies and the laboratory shall be subject to revocation for the Fields of Testing affected.

(e) No laboratory shall perform tests of environmental samples in the Field(s) of Testing affected by a deficiency, until the deficiency has been corrected and the correction has been accepted by the Department.

(f) If the laboratory has requested additional analytes, group-of-analytes, physical properties, methods, and/or Field(s) of Testing, then the application shall be handled as an amendment application with respect to timeframes as described in Section 64807(c).

Note: Authority cited: Sections 100275, 100865 and 100880, Health and Safety Code. Reference: Sections 100850, 100865 and 100880, Health and Safety Code.

§64807.030. On-site Inspection for Reinstatement of Certification after Suspension.

(a) An on-site inspection shall be conducted by the Department after receipt of an application for reinstatement after suspension of certification to determine that the laboratory will operate in compliance with Article 3 and these regulations.

(b) After reinstatement of the laboratory to full certification status, follow-up on-site inspections may be conducted by the Department to monitor compliance. Costs associated with this on-site monitoring shall be paid by the laboratory.

Note: Authority cited: Sections 100275, 100865 and 100880, Health and Safety Code. Reference: Sections 100850, 100865 and 100880, Health and Safety Code.

§64807.040. On-site Inspection for Reinstatement of Certification after Revocation.

(a) An on-site inspection shall be conducted by the Department after receipt of an application for reinstatement after revocation of certification to determine that the laboratory will operate in compliance with Article 3 and these regulations.

(b) After reinstatement of the laboratory to full certification status, follow-up on-site inspections may be conducted by the Department, as described in Section 64807, to monitor compliance Costs associated with this on-site monitoring shall be paid by the laboratory.

Note: Authority cited: Sections 100275, 100865 and 100880, Health and Safety Code. Reference: Sections 100850, 100865 and 100880, Health and Safety Code.

§64807.050. Unannounced On-site Inspections.

Unannounced on-site inspections may be conducted as necessary to determine compliance with Article 3 and the regulations adopted thereunder.

Note: Authority cited: Sections 100275, 100865 and 100880, Health and Safety Code. Reference: Sections 100850, 100865 and 100880, Health and Safety Code.

Article 5. Performance Evaluation Process

§64809. Laboratory Performance Evaluation Requirements.

(a) A laboratory certified or applying for initial certification, amendment of certification, reinstatement, and/or renewal shall participate in proficiency testing studies, as described in Section 64809.010, and shall analyze proficiency testing study samples in the matrix representative of the Field of Testing in which the laboratory is certified or requesting certification.

(b) The laboratory shall successfully participate in a proficiency testing study for each analyte, group-of-analytes, or physical property by each method for which the laboratory is certified or applying for certification.

(c) The laboratory shall produce results in a proficiency testing study that meet the acceptance criteria described in Section 64809.020.

(d) A laboratory failing to produce proficiency testing study results that meet the acceptance criteria specified in Section 64809.020, shall take corrective action(s), maintain records of such actions, and submit a corrective action summary for each failed analyte to the Department within 30 days of receipt of the evaluation report from the provider of the proficiency testing study. The corrective action summary shall include the laboratory's determination of the cause(s) for each "not acceptable" evaluation, and actions taken to improve future data quality.

(e) A laboratory not receiving an acceptable result shall cease performing the analysis with

the affected method until it has determined the causes for the failure and performed the corrective actions.

(f) No laboratory certified or seeking certification pursuant to this chapter shall submit results for evaluation in a proficiency testing study where the Department is the final recipient of the evaluated results, if the laboratory has financial interest, familial relationship, or contractual agreement in consultative capacity with the person or with the entity that provides the proficiency testing study samples.

(g) If the proficiency testing study samples are provided directly by the Department or indirectly through a third party provider designated by the Department, then the laboratory shall pay the cost for the samples directly to the Department for placement in the ELIF fund for use in the performance evaluation process of laboratories.

NOTE: Authority cited: Sections ~~208, 1011 and 1012 ,~~ 100275, 100830, and 100850, Health and Safety Code. Reference: Sections ~~1015, 1017 and 1019 ,~~ 100850, 100860.1, and 100870, Health and Safety Code.

§64809.010. Proficiency Testing Studies.

(a) Each laboratory shall analyze proficiency testing study samples by methods routinely used on real world samples received at the laboratory for regulatory purposes.

(b) The laboratory staff, who routinely perform analysis of real world samples, that are received at the laboratory for regulatory purposes, shall analyze the proficiency testing study samples.

(c) Each laboratory shall submit proficiency testing study results to the provider of the study samples by the closure date of the study. Submittal of study results after the study closure date shall be deemed a failed performance in said study.

(d) A laboratory, certified or requesting certification for the Field of Testing involving hazardous waste asbestos, shall participate in the NIST/NVLAP bulk asbestos studies provided by the National Institute of Standards and Technology (NIST) and/or the hazardous waste asbestos proficiency testing studies provided by the Department or by a third party provider designated by the Department.

(e) A laboratory, certified or requesting certification for the Fields of Testing involving environmental food, shall participate in the food proficiency testing studies provided by the Department or by the California Department of Food and Agriculture.

(f) A laboratory, certified or requesting certification for the Field of Testing involving shellfish microbiology, shall participate in the shellfish microbiology proficiency testing studies provided by the U.S. Food and Drug Administration and microbiology proficiency testing studies provided by the Department.

(g) A laboratory, certified or requesting certification for the Field of Testing involving air matrix, shall participate in the proficiency testing studies provided by the Department.

(h) A laboratory, certified or requesting certification for all other Fields of Testing, shall participate in the proficiency testing studies provided by the Department or by a third party provider designated by the Department.

NOTE: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100850, 100860.1, and 100870, Health and Safety Code.

§64809.020 Proficiency Testing Study Acceptance Criteria.

(a) Each laboratory, certified or applying for certification for a Field of Testing that involves microbiology where qualitative data is required, shall meet the acceptable response of present or absent as determined by the in-house laboratory of the proficiency testing study provider using the applicable methods of analyses in the appropriate matrix.

(b) Each laboratory, certified or applying for certification for a Field of Testing that involves microbiology where quantitative data, i.e. enumeration, is required, shall meet the acceptance limits at the 95% or 99% confidence level based on reference laboratory data dependent upon the sample matrix, the bacteria used in the sample preparation, and the method of analysis. If reference laboratory data are not available, then the in-house laboratory data of the proficiency testing study provider may be used, as long as the analyses are performed by a qualified person in microbiology.

(c) Each laboratory, certified or applying for certification for a Field of Testing that involves drinking water chemistry shall meet the acceptance criteria as specified in the Code of Federal Regulations, July 1, 2006, title 40, part 141.23(k)(3)(ii) for inorganic compounds, parts 141.23(k)(3)(ii) and 141.89(a)(1)(ii) for metals, parts 141.24(f)(17)(i) and part 141.24(f)(17)(ii) for volatile organic compounds, and part 141.24(h)(19)(i) for semi-volatile organic compounds.

(d) Each laboratory, certified or applying for certification for a Field of Testing involving drinking water or wastewater radiochemistry, shall meet the acceptance limits at the 95% or 99% confidence level, respectively, based on data from a reference laboratory, or a laboratory that meets the requirements of the National Institute of Standards and Technology in radiochemistry.

(e) Each laboratory, certified or applying for certification for a Field of Testing involving wastewater chemistry, shall meet the acceptance limits at the 99% confidence level based on reference laboratory data, or at the designated per cent from the true value designated by the U.S. Environmental Protection Agency.

(f) Each laboratory, certified or applying for certification for a Field of Testing involving aquatic bioassay, shall meet the acceptance limits at the 95% or 99% confidence level based on reference laboratory data dependent upon the matrix, the pollutant, and the method.

(g) Each laboratory, certified or applying for certification for a Field of Testing involving hazardous waste chemistry, shall meet the acceptance limits at the 99% confidence level based on reference laboratory data.

(h) Each laboratory, certified or applying for certification for a Field of Testing involving hazardous waste radiochemistry, shall meet the acceptance limits at the 99% confidence level based on data from a reference laboratory.

(i) Each laboratory, certified or applying for certification for a Field of Testing involving bulk asbestos, shall meet the acceptance criteria specified by the National Institute of Science & Technology, National Voluntary Laboratory Accreditation Program for bulk asbestos.

(j) Each laboratory, certified or applying for certification for a Field of Testing involving shellfish, shall meet the acceptance criteria as specified in the U.S. Food & Drug Administration Shellfish Laboratory Quality Assurance Program. For proficiency testing study samples provided by the Department, the laboratory shall meet the acceptance criteria of subsection (b).

(k) Each laboratory, certified or applying for certification for a Field of Testing involving environmental food, shall meet the acceptance limits at the 99% confidence level based on reference laboratory data.

(l) Each laboratory, certified or applying for certification for a Field of Testing involving air, shall meet the acceptance limits at the 99% confidence level based on reference laboratory data.

(m) Each laboratory's participation in a proficiency testing study shall be evaluated by the Department to determine acceptable performance. The following criteria shall apply where applicable:

(1) A laboratory testing for a group of organic compounds by a single method shall successfully analyze 80% or greater of representative analytes (whether present or absent in the proficiency testing study samples) by the respective method. If the laboratory fails to correctly analyze 20% or fewer of the representative analytes, then the laboratory shall participate in a subsequent proficiency testing study within a 12-month period, successfully analyze 80% or greater of representative analytes (whether present or absent in the proficiency testing study) by the same method, and obtain acceptable performance for those analytes which were evaluated as "not acceptable" in the previous study.

(2) If the group of organic compounds consists of 4 or fewer analytes, then the laboratory shall successfully analyze all representative analytes by the respective method.

(3) A laboratory result determined as a false negative or false positive for an analyte in a proficiency testing study shall be evaluated as "not acceptable" for that particular analyte.

(4) A laboratory shall not be penalized by the Department, when the validity of the proficiency testing sample is determined by the Department to be questionable based on verification, validation, homogeneity, stability, and preparation of the PT sample. The laboratory shall participate in another proficiency testing study within the following 6 months.

NOTE: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100850, 100860.1, and 100870, Health and Safety Code.

§64809.030 Frequency of Participation.

(a) A laboratory applying for certification in a Field of Testing shall participate in a minimum of one, but not more than two proficiency testing studies prior to issuance of the certificate. Where two proficiency testing studies are attempted, the studies shall be performed at a minimum of 30-days apart from the date of the first study closure and the date of commencement of the second study. The laboratory shall successfully participate in one proficiency testing study, at the earliest, sixth months prior to the date of submittal of the application or, at the latest, 6 months from the date of application submittal.

(b) A laboratory certified or applying for renewal of certification shall participate in a minimum of one, but not more than two proficiency testing studies within a 12-month period, unless otherwise stated in Section 100870 of the Health and Safety Code. Where two proficiency testing studies are attempted, the studies shall be no less than 180 days (six months) apart from the date of the first study closure and the date of commencement of the second study.

NOTE: Authority cited: Sections 100275 and 100830, Health and Safety Code. Reference: Sections 100860.0 and 100870, Health and Safety Code.

Article 6. Fields of Testing.

§64811. Fields of Testing.

(a) The laboratory shall provide to the Department the desired Fields of Testing from H&SC 100860.1(a) and include the analyte, group-of-analytes, physical property, or species along with the method for which the certificate is to be issued.

(b) The laboratory shall use only the method for which it is certified and which is applicable for the detection and/or the quantitation of the analyte, group-of-analytes, or physical property. The method shall be Federal or State approved for testing of environmental samples for the desired Field of Testing.

(c) Laboratories, certified for the Fields of Testing involving drinking water and requesting use of alternate test procedures (ATP) for Federal regulated analytes, group-of-analytes, or physical properties, shall be in compliance with the Code of Federal Regulations, July 1, 2006, title 40, part 141.27, and shall be in possession of a document from the U.S. Environmental Protection Agency that shows approval for use of the procedures, prior to their use on environmental samples. Laboratories testing for analytes, group-of-analytes, or physical properties, that are not Federal regulated but are monitored by the State, shall utilize alternate methods approved by the State.

(d) Laboratories, certified for Fields of Testing involving wastewater and requesting use of ATP for Federal regulated analytes, group-of-analytes, physical properties, or species, shall be in compliance with the Code of Federal Regulations, July 1, 2006, title 40, part 136.4, and shall be in possession of a document from the U.S. Environmental Protection Agency that shows approval for use of the procedures, prior to their use on environmental samples. Laboratories testing for analytes, or group-of-analytes, physical properties, or with species that are not Federal regulated but are monitored by the State, shall utilize alternate methods approved by the State.

(e) Laboratories, certified for hazardous waste Fields of Testing and requesting use of ATP for Federal or State regulated analytes, group-of-analytes, physical properties, or species shall be in compliance with the California Code of Regulations, Title 22, sections 66260.21(a) and 66260.21(b), and shall have been granted a variance by the California State Department of Toxic Substances Control, Environmental Chemistry Laboratory (ECL) for the procedures, prior to their use on environmental samples.

(f) For Proposition 65, each laboratory shall comply with requirements set by the Office of Environmental Health Hazard Assessment (OEHHA). For each analyte, group-of-analytes, or physical property affected by Proposition 65, the laboratory shall perform applicable analyses based on its certificate and applicable Field of Testing for the matrix of the sample.

(g) A certified laboratory, planning to modify a method which is not open to modification and where the modification is not an ATP, shall comply with the process for performance based methods described in the California State Quality Manual for Environmental Testing Laboratories of Section 64815.010.

(h) A laboratory, certified for Fields of Testing involving drinking water, wastewater, or ambient waters, shall not use performance based methods, unless otherwise stated in the Code of Federal Regulations by the U.S. Environmental Protection Agency.

(i) A certified laboratory, planning to make modification within a Federal or State approved method where such modifications are allowed as stated in the method, shall follow the process for method modifications described in the California State Quality Manual for Environmental Testing Laboratories of Section 64815.010.

Note: Authority cited: Section ~~208, 1011, and 1012,~~***100275, 100825, and 112165, 100830,*** Health and Safety Code. Reference: Sections ~~1012, 1017 and 28503~~ ***100830, 100845, 100850, 100860.1***, ***and 112165,*** Health and Safety Code; Section 12901, Title 22, California code of Regulations; Appendices I, II and III of Article 5 (commencing with Section 66261.100), Title 22, California Code of Regulations.

§64811.0100. State Approved Methods.

(a) State approved methods that are not specified in statute or regulation for the specific State monitored analyte, group-of-analytes, or physical property within a particular Field of Testing and are currently in use, appear in subsection (b) in tables 64811.0110 through 64811.1000.

(b) The State approved methods in this subsection are incorporated by reference.

Table 64811.0110 Inorganic Chemistry of Drinking Water Method References

Analyte/Group-of-Analytes	Method
MBAS (methylene blue active substances)	Standard Methods, APHA, AWWA, & WPCF, 18th (1992), 19th (1995), & 20th (1998) editions, method 5540C
perchlorate	Determination of Perchlorate in Drinking Water Using Ion Chromatography, November 1999, U.S. Environmental Protection Agency, method 314.0
potassium	Standard Methods, APHA, AWWA, & WPCF, 18th (1992) & 19th (1995) editions, method 3500-K D
	Standard Methods, APHA, AWWA, & WPCF, 20th (1998) edition, method 3500-K B

Table 64811.0120 Toxic Chemical Elements of Drinking Water Method References

Metals	Methods
boron	Methods for the Determination of Metals in Environmental Samples, U.S. Environmental Protection Agency, May 1994, EPA/600/R-94/111, method 200.8
chromium (VI)	Methods for the Determination of Metals in Environmental Samples, U.S. Environmental Protection Agency, May 1994, EPA/600/R-94/111, method 218.6
vanadium	Methods for the Determination of Metals in Environmental Samples, U.S. Environmental Protection Agency, May 1994, EPA/600/R-94/111, method 200.9

Table 64811.0130 Volatile Organic Chemistry of Drinking Water Method References

Analyte/Group-of-Analytes	Method
t-amyl methyl ether (TAME), t-butyl alcohol (TBA), ethyl-t-butyl ether (ETBE), methyl-t-butyl either (MTBE), dichlorodifluoromethane (Freon 12), trichlorofluoromethane (Freon 11), 1,1,2-trichloro-1,2,2-trifluoroethane (Freon 113)	Methods for the Determination of Organic Compounds in Drinking Water, U.S. Environmental Protection Agency, August 1995, EPA/600/R-95/131, methods 502.2 and 524.2
1,2,3-trichloropropane	methods 524.2M and 525.2M, California State Department of Health Services, Sanitation & Radiation Laboratory Branch, ATTN: Branch Chief

Table 64811.0140 Semi-Volatile Organic Chemistry of Drinking Water Method References

Analyte/Group-of-Analytes	Method
dioxins	Methods for the Determination of Organic Compounds in Drinking Water, U.S. Environmental Protection Agency, October 1994, EPA 821-B-94-005, method 1613

Table 64811.0150 Radiochemistry of Drinking Water Method References

Analyte/Group-of-Analytes	Method
radon-222	Standard Methods, APHA, AWWA, & WPCF, 1996, 19th edition, supplement, method 7500-Rn
	Standard Methods, APHA, AWWA, & WPCF, 1998, 20th edition, method 7500-Rn B
	Two Test Procedures for Radon in Drinking Water Interlaboratory Collaborative Study, U.S. Environmental Protection Agency, March 1987, EPA/600/2-87/082, p. 22, Appendix D (The Determination of Radon in Drinking Water)

Table 64811.0160 Inorganic Chemistry of Wastewater Method References

Analyte/Group-of-Analytes	Method
tannin and lignin	Standard Methods, APHA, AWWA, & WPCF, 1992, 18th edition, method 5550B
total recoverable petroleum hydrocarbons	Methods for Chemical Analysis of Water and Wastes, March 1983, EPA-600/4-79-020, method 418.1

Table 64811.0170 Toxic Chemical Elements of Wastewater Method References

Analyte/Group-of-Analytes	Method
asbestos	Analytical Methods for Determination of Asbestos Fibers in Water, U.S. Environmental Protection Agency, September 1983, EPA-600/4-83-043, method 100.1
	Method 100.2, Determination of Asbestos Structures over 10 um in Length in Drinking Water, U.S. Environmental Protection Agency, June 1994, EPA/600/R-94/134, method 100.2, available through NTIS number PB 83-260471

Table 64811.0180 Semi-volatile Organic Chemistry of Wastewater Method References

Analyte/Group-of-Analytes	Method

carbamates	The Determination of Carbamates and Urea Pesticides in Industrial and Municipal Wastewater, U.S. Environmental Protection Agency, method 632, available through California State Department of Health Services, Environmental Laboratory Accreditation Program, ATTN: Duty Officer
dioxins	Methods for the Determination of Organic Compounds in Drinking Water, U.S. Environmental Protection Agency, October 1994, EPA 821-B-94-005, method 1613

Table 64811.0190 Radiochemistry of Wastewater Method References

Analyte/Group-of-Analytes	Method
radionuclides, excluding gross alpha, gross beta, total radium, radium-226	Prescribed Procedures for Measurement of Radioactivity in Drinking Water, U.S. Environmental Protection Agency, August 1980, EPA-600/4-80-032, available through NTIS number PB 80-224744
	Radiochemistry Procedures Manual, U.S. Environmental Protection Agency, December 1987, EPA-520/5-84-006, available through NTIS number PB 84-215581
	Radiochemical Analytical Procedures for Analysis of Environmental Samples, U.S. Environmental Protection Agency, March 1979, available through NTIS number EMSL-LV-0539-17
	Methods for Determination of Radioactive Substances in Water and Fluvial Sediments, U.S. Geological Survey, 1997, Book 5, Chapter A5, available through U.S. Geological Survey, Denver, CO
	EML Procedures Manual, U.S. Department of Energy, 25th (1982) edition, 26th (1984) edition, 27th (1990) edition, volume 1, and 28th (1997) edition, volumes 1 & 2, available through Environmental Measurements Laboratory, U.S. Department of Energy, New York, NY
uranium	Standard Methods, APHA, AWWA, & WPCF, 18th (1992), 19th (1995), & 20th (1998) editions, method 7500-U C

Table 64811.0200 Whole Effluent Toxicity of Wastewater Method References

Analyte/Group-of-Analytes	Method
aquatic organisms excluding those in 40 CFR 136.3	Methods for Measuring the Toxicity and Bioaccumulation of Sediment-associated Contaminants with Freshwater Invertebrates, U.S. Environmental Protection Agency, June 1994, EPA/600/R-94/024

	Methods for Assessing the Toxicity of Sediment-associated Contaminants with Estuarine and Marine Amphipods, U.S. Environmental Protection Agency, June 1994, EPA/600/R-94/025
	Procedures Manual for Conducting Toxicity Tests Developed by the Marine Bioassay Project, State Water Resources Control Board, California Environmental Protection Agency, January 1996, 96-1WQ
	Static Acute Bioassay Procedures for Hazardous Waste Samples, California Department of Fish and Game, Water Pollution Control Laboratory, November 1988
	Standard Guide for Conducting Static Acute Toxicity Tests Starting with Embryos of Four Species of Saltwater Bivalve Molluscs, American Society for Testing & Materials, Philadelphia, PA, E 724-89, 1994, method ASTME724-94
	Standard Guide for Conducting Static 96-h Toxicity Tests with Microalgae, American Society for Testing & Materials, Philadelphia, PA, E 1218-90, 1990, method ASTME1218-90

Table 64811.0210 Inorganic Chemistry and Toxic Chemical Elements of Hazardous Waste Method References

Analyte/Group-of-Analytes	Method
organic lead	HML Method 939-M, California Department of Toxic Substances Control, Environmental Chemistry Laboratory (ECL), available through ECL

Table 64811.0220 Volatile Organic Chemistry of Hazardous Waste Method References

Analyte/Group-of-Analytes	Method
TPH gasoline	8015B, U.S. Environmental Protection Agency, December 1996, SW846 series, update III
	ECL Method 815-M, California Department of Toxic Substances Control, Environmental Chemistry Laboratory (ECL), available through ECL
	Leaking Underground Fuel Tank Field Manual, Guidelines for Site Assessment, Cleanup, and Underground Storage Tank Closure, (LUFT manual), State of California Leaking Underground Fuel Tank Task Force, Department of Toxic Substances Control, October 1989

Table 64811.0230 Semi-volatile Organic Chemistry of Hazardous Waste Method References

Analyte/Group-of-Analytes	Method

TPH diesel	8015B, U.S. Environmental Protection Agency, December 1996, SW846 series, update III
	ECL Method 816-M, California Department of Toxic Substances Control, Environmental Chemistry Laboratory (ECL), available through ECL
	Leaking Underground Fuel Tank Field Manual, Guidelines for Site Assessment, Cleanup, and Underground Storage Tank Closure, (LUFT manual), State of California Leaking Underground Fuel Tank Task Force, Department of Toxic Substances Control, October 1989

Table 64811.0240 Radiochemistry of Hazardous Waste Method References

Analyte/Group-of-Analytes	Method
radionuclides, excluding gross alpha/beta, total alpha radium & radium-228 in aqueous matrices	Prescribed Procedures for Measurement of Radioactivity in Drinking Water, U.S. Environmental Protection Agency, August 1980, EPA-600/4-80-032, available through NTIS number PB 80-224744
	Radiochemistry Procedures Manual, U.S. Environmental Protection Agency, June 1984, EPA-520/5-84-006, available through NTIS number PB 84-215581
	Radiochemical Analytical Procedures for Analysis of Environmental Samples, U.S. Environmental Protection Agency, March 1979, available through NTIS number EMSL-LV-0539-17
	Methods for Determination of Radioactive Substances in Water and Fluvial Sediments, U.S. Geological Survey, 1997, Book 5, Chapter A5, available through U.S. Geological Survey, Denver, CO
	EML Procedures Manual, U.S. Department of Energy, 25th (1982) edition, 26th (1984) edition, 27th (1990) edition volume 1, and 28th (1997) volumes 1 & 2, available through Environmental Measurements Laboratory, U.S. Department of Energy, New York, NY
gamma fission products (screen)	EML Procedures Manual, U.S. Department of Energy, 1997, 28th edition, volume 1, method Ga-01-R, with "Sample Preparation and Analysis", U.S. Department of Energy, August 1998, available through California Department of Health Services, Environmental Management Branch

Table 64811.0250 Toxicity Bioassay of Hazardous Waste Method References

Analyte/Group-of-Analytes	Method

aquatic organisms excluding those in 22CCR 66261.24(a)(6)	Methods for Measuring the Toxicity and Bioaccumulation of Sediment-associated Contaminants with Freshwater Invertebrates, U.S. Environmental Protection Agency, June 1994, EPA/600/R-94/024
	Methods for Assessing the Toxicity of Sediment-associated Contaminants with Estuarine and Marine Amphipods, U.S. Environmental Protection Agency, June 1994, EPA/600/R-94/025
	Static Acute Bioassay Procedures for Hazardous Waste Samples, California Department of Fish & Game, Water Pollution Control Laboratory, November 1988

Table 64811.0260 Bulk Asbestos Analysis of Hazardous Waste Method References

Analyte/Group-of-Analytes	Method
asbestos	Interim Method for the Determination of Asbestos in Bulk Insulation Samples, U.S. Environmental Protection Agency, December 1982, EPA-600/M4-82-020, available through NTIS

Table 64811.0270 Microbiology of Food Method References

Analyte/Group-of-Analytes	Method
micro-organisms	Bacteriological Analytical Manual, Food & Drug Administration, 1995, 8th edition
	Compendium of Methods for the Microbiological Examination of Foods, American Public Health Association, 4th edition
	Official Methods of Analysis, William Horwitz (ed), 2000, 17th edition
	Compendium of Analytical Methods, Health & Welfare Canada, Health Protection Branch, January 2002, volume 1
	Compendium of Analytical Methods, Health & Welfare Canada, Health Protection Branch, January 2002, volume 2
	Compendium of Analytical Methods, Health & Welfare Canada, Health Protection Branch, January 2002, volume 3
	Compendium of Analytical Methods, Health & Welfare Canada, Health Protection Branch, April 1999, volume 4
	Microbiology Laboratory Guidebook, U.S. Department of Agriculture, Food Safety Inspection Service, 1998, 3rd edition

Table 64811.0280 Pesticide Residues in Food Method References

Analyte/Group-of-Analytes	Method

organic compounds	Pesticide Analytical Manual, 1992, volumes I and II, U.S. Department of Health & Human Services, Public Health Service, U.S. Food and Drug Administration, 2905A
	CDFA Multi-Residue Pesticide Screening Method, California Department of Food and Agriculture, Center for Analytical Chemistry, contact QA Officer
	Journal of Agricultural and Food Chemistry, 1991, volume 39, number 9, page 1658, "Solid-Phase Extraction Cleanup of Halogenated Organic Pesticides"
	Bulletin of Environmental Contamination and Toxicology, 1984, volume 33, page 538, "High Performance Liquid Chromatographic Methods for Determination of n-Methyl Carbamates in Fruits and Vegetables"
	Official Methods of Analysis of AOAC International, 2000, 17th edition, section 10
	Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed, U.S. Food and Drug Administration, Industry Activities Staff (HFS-565) CFSAN/FDA
	Food Testing and Analysis, April/May 2000, volume 6, page 2, "The Basic Concepts of Pesticide Residue Analyses in Food Crops"
	Journal of Chromatography, 1995, volume 690, pages 455, "Off-line High Performance Liquid Chromatography and Solid Phase Extraction Clean-up for Confirmation of Pesticide Residues in Fresh Produce by Gas Chromatography Mass Spectroscopy"
	Journal of AOAC, 1991, volume 74, page 6, "GC-MIP-AED Method for Pesticide Residue Determination in Fruits and Vegetables"

Table 64811.0290 Recreational Water Method References

Analyte/Group-of-Analytes	Method
micro-organisms	Federal Register, August 30, 2001, volume 66, number 169, table 1A
	Federal Register, July 21, 2003, volume 68, number 139

Table 64811.0300 Shellfish Method References

Analyte/Group-of-Analytes	Method
micro-organisms, meat, shellfish growing waters, shellfish toxins	Recommended Procedures for the Examination of Sea Water and Shellfish, American Public Health Association, 1970, 4th edition

	Official Methods of Analyses of the Association of Official Analytical Chemists, AOAC, 15th edition (1990), & 17th edition (2000), volume 1, chapter 17, method 978.23
	Microbiological Methods for Monitoring the Environment, Water and Wastes, U.S. Environmental Protection Agency, 1978, EPA/600/8/78/017

Note: authority cited: Sections 100275, 100825, and 100830, Health and Safety Code. Reference: Sections 100830, 100845, 100850, 100860.1, and 112165, Health and Safety Code.

Article 7. Laboratory and Equipment

Section 64813. Laboratory and Equipment.

(a) A laboratory shall be arranged and operated so that:

(1) utilities are maintained to the degree necessary to allow the laboratory equipment to function and produce accurate analyses and test results in each Field of Testing for which the laboratory is certified; and

(2) ventilation and environmental control are maintained in the laboratory so that analytical results are not adversely affected beyond established quality control limits as specified in the approved methods or in the laboratory's quality assurance manual; and

(3) the design, arrangement, and operation of the laboratory minimizes the potential for sample contamination; and

(4) the storage and handling of hazardous materials in accordance with the California Code of Regulations, Title 8, General Industry Safety Orders, Department of Industrial Relations; and

(5) the disposal of chemical wastes is in accordance with the California Code of Regulations, Title 22, Division 4.5, Environmental Health Standards for the Management of Hazardous Wastes, State of California, Department of Health Services.

(b) Each piece of laboratory equipment shall meet all operational, quality assurance, quality control, and design criteria established in the method(s) employed by the laboratory, and where applicable meet the requirements that appear in Section 64815.010.

(c) Each piece of laboratory equipment shall be operated and maintained by the laboratory as specified by the manufacturer.

(d) Records shall be kept of all operational and maintenance activities associated with the operation of laboratory equipment.

Note: Authority cited: Sections ~~208, 1011 and 1012~~***100275, 100825, and 100830***, Health and Safety Code. Reference: Section ~~1012~~***100830***, Health and Safety Code; California Code of Regulations, Title 8; and Title 22, Division 4, Chapter 30, California Code of Regulations.

Article 8. Quality Assurance

Section 64815. Quality Assurance Documents.

(a) Each laboratory shall develop and implement a quality assurance program to assure the reliability and validity of the analytical data produced by the laboratory. As evidence of such a program, the laboratory shall develop and maintain a quality assurance program manual.

(b) The quality assurance program manual shall address all quality assurance and quality control practices to be employed by the laboratory and shall, at least, include the quality assurance and quality control requirements specified in the methods for which the laboratory holds, or seeks, certification. The manual shall include the following elements: laboratory organization and personnel responsibilities; quality assurance objectives for measurement data; sampling procedures (when the laboratory performs the sampling); custody, handling, and disposal of samples; calibration procedures and frequency; analytical procedures; acquisition and reduction, validation and reporting of data; internal quality control checks; performance and system audits; preventive maintenance; assessment of precision and accuracy; corrective action; and quality assurance reports.

(c) The director of the laboratory shall be responsible for ensuring that the quality assurance program and quality assurance program manual are reviewed at least annually. The director of the laboratory shall also review and amend the quality assurance program and manual whenever there are changes in methods or laboratory equipment employed, in the laboratory structure or physical arrangements, or changes in the laboratory organization.

(d) The laboratory shall maintain records of the implementation of its quality assurance program, and provide those records upon request of the Department. Records shall be maintained for no less than the time period for retention of records of data and all supporting documentations required by the applicable government programs.

Note: Authority cited: Sections ~~208 and 1011~~100275 and 100830, Health and Safety Code. Reference: Section ~~1012~~100830, Health and Safety Code.

Section 64815.010. Quality Manual.

(a) Each laboratory shall comply with the California State Quality Manual for Environmental Testing Laboratories, 2007, produced by the Department to ensure reliability of data generated by the laboratory.

(b) The California State Quality Manual for Environmental Testing Laboratories, 2007, ELAP-01-2007, is incorporated by reference to this section.

Note: Authority cited: Sections 100830, Health and Safety Code. Reference: Section 100830, Health and Safety Code.

§64816. Records Retention.

(a) The laboratory shall maintain its current records on the premises in a filing system that is organized and structured such that requested records are retrievable within a one- to two-hour time frame upon request. "Current records" for this section shall apply to the records generated, used, or acquired at the minimum within the last 24 months of the operation of the laboratory.

(b) The laboratory shall maintain archived records in a filing system that is organized and structured such that requested records are retrievable within 24 hours, not to exceed three working days. "Archived records" for this section shall apply to any records generated, used, or acquired at the minimum over 24 months from the present date of operation.

(c) The room designated for record retention shall be secured, clean, and free from chemicals, samples, and other material which could contaminate, corrode, or destroy the records. If a separate room cannot be allocated for the records, then the records shall be maintained in a locked cabinet that cannot be readily removed from the premises.

(d) Records shall be retained at a minimum for the timeframe designated by the program for which the data was acquired. "The program" for this section applies to the environmental testing program established by the Federal, State, or local government entities. Record retention times are included, but not limited to retention periods specified in the California State Quality Manual for Environmental Testing Laboratories, found at Section 64815.010.

(e) Personnel records, training records, and other administrative records shall be retained in accordance to law regarding such records.

(f) The laboratory shall have documented plans in the handling of its records which includes and is not limited to the following items:

(1) tracking of the records through the laboratory;

(2) scheduling archive of records;

(3) monitoring retrieval of records from storage and return of records to storage;

(4) establishing contacts with government entities who are the final recipients of the data generated by the laboratory, and documenting the contacts names, telephone numbers, Departments, and locations for further reference in the event the records have exceeded the retention time and is no longer needed by the laboratory;

(5) documenting disposition of records once retention times have been exceeded and the records are no longer needed by the laboratory;

(6) type of documentations of the records for storage shall contain sufficient information for tracking of the sample, the date of analysis, the client name, storage number, storage location, and any other necessary information for tracking.

(g) When the record retention times have been exceeded and the records are no longer needed by the laboratory, the laboratory shall contact the government entity that is the final recipient of the data generated by the laboratory for the affected records, and obtain disposition instructions for the records. The laboratory shall be responsible for the cost for disposition of the records.

(h) Prior to closure of the laboratory, the laboratory shall comply with section (g) above,

(i) If electronic data and other documents are to be retained for future reference, the following shall apply:

(1) the laboratory shall retain records such that all records can be successfully reconstructed when necessary;

(2) the laboratory shall retain a printout of the electronic data and other documents immediately after the data or documents are produced or received;

(3) the laboratory shall place in storage with the electronic data and other documents, the software necessary for reading, copying and printing the electronic data and other documents, the compatible computer, and printer (unless the laboratory can show that the software is compatible with current hardware);

(4) the laboratory shall ensure that the initial electronic copy of the data and other documents is accurate;

(5) if the electronic data and other documents are on a CD, tape, DVD, floppy disc, hard disc, or other electronic format, the laboratory shall have established and implemented a standard operating procedure in order to prevent data corruption, unusable data, and other anomalies associated with decay of the medium, deterioration/malfunction of the computer, and problems commonly associated with software;

(6) the laboratory shall have established and implemented a testing process, that includes the frequency for the test to ensure that the stored equipment and software continue to function appropriately.

Note: Authority cited: Sections 100830, Health and Safety Code. Reference: Section 100830, Health and Safety Code.

Article 9. Laboratory Personnel.

§64817. Director.

(a) Each laboratory shall designate a director. Except as provided in Subsections (b) and/or (c), the director shall have as a minimum:

(1) Documentation of the director's education including:

(A) Official transcripts from the registrar of all accredited colleges or universities attended by the applicant showing all courses, course credits, degrees conferred and date of conference of a baccalaureate of science degree in chemistry, biochemistry, biology, microbiology, or physical science and is applicable to the Fields of Testing performed at the laboratory; and

(B) Official transcripts from non-United States colleges or universities which are not in English shall be returned to the applicant to obtain translation from a translation service approved in the United States for legal or government documents.

(C) Official transcripts and other documentation of education shall be made available upon request.

(2) Documentation of his/her experiences including at least three years work experience in the analysis of water, wastewater, solid waste, hazardous waste or other environmental samples that are applicable for the types of work performed by the laboratory.

(A) A master of science degree in chemistry, biochemistry, biology, microbiology, or physical science may be substituted for one year of the required experience.

(B) A doctorate in chemistry, biochemistry, biology, microbiology, or physical science may be substituted for two years of the required experience.

(b) In lieu of meeting the requirements specified in Subsection (a), a director employed by a laboratory owned by a public drinking water or wastewater utility shall possess a Laboratory Analyst/Water Quality Analyst Certificate from the California Water Environment Association (CWEA) or the California-Nevada Section of the American Water Works Association (CA-NV/AWWA), pursuant to the Fields of Testing Conversion Table for Director Capacity. The minimum grade of the above certificate acceptable to the Department shall be based on the Fields of Testing for which the laboratory seeks certification as noted in the table.

FIELDS OF TESTING CONVERSION TABLE FOR DIRECTOR CAPACITY	
Fields of Testing	**Minimum Certificate Grade Required**
101, 102[a], 107 and 108[b]	I
101, 102, 107, 108, 113 and 119	II
103, 104[c], 105[c], 108, 110[c], 111[c] and those allowed for a Grade II	III
104, 105, 106, 110, 111, 112 and those allowed for a Grade III	IV

Footnotes for the Fields of Testing Conversion Table for Director Capacity:
a. Limited to testing for: alkalinity, chloride, hardness, total filterable residue, and conductivity.
b. Limited to testing for: acidity, alkalinity, biochemical oxygen demand, chemical oxygen demand, chlorine residual, hardness, dissolved oxygen, pH, total residue, filterable residue, nonfilterable residue, settleable residue, volatile residue, specific conductance, and turbidity.
c. Excluding methods that require the use of GC/MS.

(c) All directors of laboratories certified by the Department on or before December 31, 1994 shall be exempt from meeting the requirements of (a) or (b) above.

(d) A director shall not serve as a nominal director and shall be responsible for:

(1) All analytical and operational activities of the laboratory, including those of any auxiliary laboratory; and

(2) Supervision of all personnel employed by the laboratory, including those assigned to work in any auxiliary laboratory; and

(3) The accuracy and quality of all data reported by the laboratory, including any auxiliary laboratory.

(e) A director shall assume the position of, or shall designate another person(s) as, the supervisor and/or analyst responsible for the use of a sophisticated laboratory instrument, or other instrument in the laboratory. However, if the director reapportions performance of any of his or her responsibilities or duties, he or she shall remain responsible for ensuring that all duties and responsibilities are properly performed.

(f) A director shall assume the responsibilities, or shall designate another person, to monitor quality assurance of all work performed in the laboratory. However, if the director reapportions performance of any of his or her responsibilities or duties, he or she shall remain responsible for ensuring that all duties and responsibilities are properly performed.

(g) If the laboratory intends to continue to engage in environmental laboratory testing after a director has relinquished over-site and control of the laboratory an interim director meeting the requirements of Article 3 of the Health and Safety Code and these regulations shall be appointed within 5 business days.

(h) The interim director may serve as director for a period not to exceed ninety days, provided that the laboratory notifies the Department, in writing, within 30 days of the appointment, describing the qualifications of the temporary director and receives written confirmation from the Department.

Note: Authority cited: Sections ~~208, 1011 and 1012~~***100275, 100825, and 100830***, Health and Safety Code. Reference: Section ~~1012~~***100830***, Health and Safety Code.

§64817.010. Quality Assurance Officer.

(a) The duties and responsibilities of the quality assurance officer shall be clearly identified by the director of the laboratory.

(b) No person shall be a quality assurance officer unless he/she has met the following qualifications:

(1) Possesses at least a baccalaureate of science degree in chemistry, biochemistry, biology, microbiology, or physical science, that is applicable to the Fields of Testing performed by the laboratory; and

(2) Has documentation of his/her education including:

(A) Official transcripts from the registrar of all accredited colleges or universities attended by the quality assurance officer showing all courses, course credits, degrees conferred and date of conference of the baccalaureate of science degree; and

(B) Official transcripts from non-United States colleges or universities which are not in English shall be returned to the applicant to obtain translation from a translation service approved in the United States for legal or government documents.

(C) Official transcripts and other documentation of education shall be made available upon request.

(3) Has documentation of his/her training including certificate of participation in, and completion of, courses taught by the manufacturers of the sophisticated laboratory instruments which are being used in the laboratory; and

(4) Has documentation of his/her experiences including at least two years experience in the analysis of air, water wastewater, solid waste, hazardous waste or other environmental samples that are applicable for the types of work performed by the laboratory. The experience requirement shall be satisfied from work experience applicable to the Fields of Testing performed at the laboratory prior to the person having obtained the position of a quality assurance officer of the laboratory.

(A) A master of science degree in chemistry, biochemistry, biology, microbiology, or physical science may be substituted for one year of the required experience.

(B) A doctorate in chemistry, biochemistry, biology, microbiology, or physical science may be substituted for two years of the required experience.

(c) All quality assurance officers of laboratories that were certified by the Department prior to January 01, 2007 shall be exempt from meeting the requirements of (b) above.

(d) The quality assurance officer shall not serve as a nominal quality assurance officer, and shall be responsible for all quality assurance activities, including providing to the laboratory director and the owner of the laboratory appropriate advice, suggestions for resolution of problems that may exist or become evident through his/her internal audits.

(e) In the absence of the quality assurance officer from the laboratory, the director shall reassume the responsibilities of quality assurance or designate and train a laboratory employee of similar or equal qualifications to take on the function of the quality assurance officer.

Note: Authority cited: Sections 100275, 100825, and 100830, Health and Safety Code. Reference: Section 100830, Health and Safety Code.

§64817.020. Supervisor.

(a) No person shall be a supervisor for a laboratory unless he or she is:

(1) The user of the sophisticated laboratory instrument, and/or other instrument/equipment; and

(2) The supervisor of the users of the sophisticated laboratory instrument and/or other laboratory staff.

(b) Except as provided in (c) below, no person shall be a supervisor unless he or she meets the following educational and experience requirements:

(1) Possesses at least a baccalaureate of science degree in chemistry, biochemistry, biology, microbiology, or physical science, that is applicable to the Fields of Testing performed at the laboratory; and

(2) Has documentation of his/her education including:

(A) Official transcripts from the registrar of all accredited colleges or universities attended by the supervisor showing all courses, course credits, degrees conferred and date of conference of the baccalaureate of science degree; and

(B) Official transcripts from non-United States colleges or universities which are not in English shall be returned to the applicant to obtain translation from a translation service approved in the United States for legal or government documents.

(C) Official transcripts and other documentation of education shall be made available upon request.

(3) Has documentation of his/her training including a certificate of participation in, and completion of, a course taught by the manufacturer of the particular sophisticated laboratory instrument which is being used or supervised by the supervisor; and

(4) Has documentation of his/her experiences including at least six months experience in the operation of a sophisticated laboratory instrument in the analysis of air, water, wastewater, solid waste, hazardous waste or other environmental samples, including food. This experience requirement must be satisfied from experience gained prior to obtaining the position of supervisor.

(5) Has at least two years documented experience in the analysis of air, water, wastewater, solid waste, hazardous waste or other environmental samples that are applicable for the types of work performed by the laboratory. The experience requirement shall be satisfied from work experience applicable to the Fields of Testing performed at the laboratory prior to the person having obtained the position of a supervisor of the laboratory.

(A) A master of science degree in chemistry, biochemistry, biology, microbiology, or physical science may be substituted for one year of the required experience.

(B) A doctorate in chemistry, biochemistry, biology, microbiology, or physical science may be substituted for two years of the required experience.

(c) In lieu of meeting the requirements specified in Subsection (b), supervisors of utility-owned water or wastewater treatment plant laboratories performing any analyses under Section 4025 of the Health and Safety Code, or Section 13176 of the Water Code may fulfill the requirements for supervisor by possession of a Laboratory Analyst/Water Quality Analyst Certificate from the California Water Pollution Control Association (CWPCA) or the California-Nevada Section of the American Water Works Association (CA-NV/AWWA). The minimum grade of the above certificate acceptable to the Department shall be based on the Fields of Testing for which the laboratory seeks certification as noted in the Fields of Testing Conversion Table for Director Capacity in Section 64817.

(d) All supervisors of laboratories that were certified by the Department as of December 31, 1994 shall be exempt from meeting the requirements of (b) or (c) above.

Note: Authority cited: Sections ~~208, 1011 and 1012~~***100275, 100825, and 100830***, Health and Safety Code. Reference: Section ***100830***~~1012~~, Health and Safety Code.

§64817.030. Analyst.

(a) No person shall be an analyst unless he/she has met the following qualifications:

(1) Possesses at least a baccalaureate of science degree in chemistry, biochemistry, biology, microbiology, or physical science, that is applicable to the Field(s) of Testing performed at the laboratory; and

(2) Has documentation of his/her education including:

(A) Official transcripts from the registrar of all accredited colleges or universities attended by the analyst showing all courses, course credits, degrees conferred and date of conference of the baccalaureate of science degree; and

(B) Official transcripts from non-United States colleges or universities which are not in English shall be returned to the applicant to obtain translation from a translation service approved in the United States for legal or government documents.

(C) Official transcripts and other documentation of education shall be made available upon request.

(3) Has documentation of his/her training including a certificate of participation in, and completion of, a course taught by the manufacturer of the particular sophisticated laboratory instrument which is being used by the analyst; and

(4) Has at least one month of documented hands-on training in the operation of a sophisticated laboratory instrument in the analysis of air, water, wastewater, solid waste, hazardous waste or other environmental samples, including food, as described in the California State Quality Manual for Environmental Testing Laboratories in Section 64815.010. This training requirement must be completed prior to analyses of samples for regulatory purposes with such sophisticated laboratory instruments.

(5) Has documentation of his/her experiences including at least one year experience in the analysis of air, water, wastewater, solid waste, hazardous waste or other environmental samples that are applicable for the types of work performed by the laboratory. The experience requirement shall be satisfied from work experience applicable to the Fields of Testing performed at the laboratory prior to the person having obtained the position of an analyst of the laboratory.

Note: Authority cited: Sections 100275, 100825, and 100830, Health and Safety Code. Reference: Section 100830, Health and Safety Code.

§64817.040. Technician.

(a) No person shall perform the duties of a technician unless he/she has met the following qualifications:

(1) Possesses at least an associate of arts degree in a science oriented discipline, that is applicable to the Fields of Testing performed at the laboratory; and

(2) Has documentation of his/her education including:

(A) Official transcripts from the registrar of all accredited colleges attended by the technician showing all courses, course credits, degrees conferred and date of conference of the associate of arts degree; and

(B) Official transcripts from non-United States colleges which are not in English shall be returned to the applicant to obtain translation from a translation service approved in the United States for legal or government documents.

(C) Official transcripts and other documentation of education shall be made available upon request.

(3) Has documented completion of the courses specified in Section 64815.010; and

(4) Has documented and completed training provided by the laboratory involving operation of the instruments/equipment and procedures utilized in the methods for the analyses of the various matrices associated with the Fields of Testing performed at the laboratory. The training shall meet the specifications in Section 64815.010.

Note: Authority cited: Sections 100275, 100825, and 100830, Health and Safety Code. Reference: Section 100830, Health and Safety Code.

§64817.050. Assistant.

(a) An assistant may perform sample receiving, sample handling, sample preparation, chain-of-custody functions, reagent preparation, calibration checks of micro-pipetters, and other similar duties that do not require knowledge in college level chemistry, microbiology, or other discipline required for carrying out the duty.

(b) No person shall perform the duties of an assistant unless he/she has met the following qualifications:

(1) Possesses at least a high school diploma with a major in a science oriented discipline, that is applicable to the Fields of Testing performed at the laboratory; and

(2) Has documentation of his/her education including:

(A) Official transcripts from the registrar of the high school attended by the assistant showing all courses, course credits, diploma conferred and date of conference of the high school diploma; and

(B) Official transcripts from non-United States colleges which are not in English shall be returned to the applicant to obtain translation from a translation service approved in the United States for legal or government documents.

(C) Official transcripts and other documentation of education shall be made available upon request.

(2) Has documented completion of the courses specified in Section 64815.010; and

(3) Has documented and completed training provided by the laboratory involving operation of the general laboratory equipment and procedures utilized in the methods for the duties specified in subsection (a) above. The training shall meet the specifications in Section 64815.010.

Note: Authority cited: Sections 100275, 100825, and 100830, Health and Safety Code. Reference: Section 100830, Health and Safety Code.

Article 10. Notification and Reporting.

§64819. Notification and Reporting to Meet ELAP Accreditation Purposes.

(a) A laboratory certified by the Department shall comply with the reporting requirements specified in Section 64815.010.

(b) The laboratory shall report all detected pollutants and contaminants from the analyses of the sample or components thereof to its clients.

(c) The laboratory shall immediately notify its clients when analyses of samples or components thereof results in data at or exceeding the maximum contaminant levels (MCL) or the action levels of the pollutants and/or contaminants. The laboratory shall document the notification with the date, time, and client (contact) name and telephone number for future reference. The laboratory is responsible in making arrangements for notification with a government office in the event the laboratory is not able to converse with the client, as required.

(d) The director of the laboratory shall notify the Department in writing of any changes to personnel, laboratory instrument/equipment, and quality assurance manual within 30 days from the date of the change. If the changes prevent the laboratory from functioning within a Field of

Testing, then the laboratory shall include in its notification to the Department of the date of inactivity with its plans for the disposition of affected samples and other future plans.

(e) In the event of a change-in-ownership of a certified laboratory, the new and previous Owners shall be responsible for notification, in writing, of such a change to the Department within 15 days after the change and shall report any occurrences since the change as specified in Section 64827.

(f) If a laboratory holds a certificate issued from the Department through reciprocity with another state, and the laboratory has a change in certification status with that state, then the laboratory shall notify the Department of the change in status within 10 calendar days of the change.

(g) Laboratories certified for Fields of Testing of food shall verify the identity and quantity of a pesticide residue before reporting the results. The confirmation procedures must conform to those that appear in the methods approved by the California Department of Food and Agriculture.

(h) In any arrangements between laboratories involving the transfer of samples, or portions of samples, the laboratory issuing the report of analyses shall include the original of any report(s) (or copy of the original) prepared by all other laboratories who are party to the agreement.

Note: Authority cited: Sections 100275, ***100825 and*** 100830, ~~100835 and 116375~~, Health and Safety Code. Reference: Sections 100825~~(b)~~ and ~~100835~~***100830***, Health and Safety Code.

Article 11. Reciprocity Agreements.

§64821. Reciprocity Agreements.

(a) Another State's, or a United States agency's environmental laboratory certification, accreditation, or licensing program shall be recognized for the purposes of reciprocity if that program requires:

(1) evaluation of participating laboratories through periodic analyses of proficiency testing study samples with the frequency of submittal, the method of evaluation, and the established acceptance limits at least equal to those established in Section 64809 of this Chapter;

(2) on-site evaluation of participating laboratories during which the laboratory is reviewed under criteria at least equal to that established in Sections 64807 through 64807.050 of this Chapter;

(3) standards for quality assurance, laboratory facilities, methods, laboratory equipment, and personnel for participating laboratories at least equal to those in Sections 64811, 64813, 64815, 64815.010, 64817, and 64817.010 through 64817.050 of this Chapter.

(b) Where reciprocity exists, each laboratory seeking California certification shall submit:

(1) an application pursuant to Section 64805 of this Chapter;

(2) copies of the results evaluated, or scored, from the last proficiency testing study in which the laboratory participated for the other program;

(3) copies of the last on-site evaluation report prepared by the other program and the laboratory's response to any deficiencies noted;

(4) all applicable fees pursuant to Health and Safety Code, Section 100860.1; and

(5) a copy of the certificate, license, permit, or authorization to operate as an environmental laboratory issued to the laboratory by the other agency.

(c) When a reciprocity agreement exists between the Department and another State, only those laboratories that reside within the boundaries of the other State shall be eligible for certification through reciprocity.

(d) If a reciprocity agreement with another State, or U.S. government agency is rescinded, all certificates issued by the Department to all affected laboratories shall remain valid until the stated expiration date.

(e) No fees are waived where reciprocity exists.

(f) A laboratory certified under reciprocity may be visited or issued proficiency testing study samples by the Department for the purposes of addressing questions or concerns on quality of results raised by any California government agency who has received a report from the laboratory. Applicable proficiency testing study sample costs, pursuant to Section 100870 or travel costs pursuant to Section 100860.1 of the Health and Safety Code or Section 64809 shall be paid.

(g) If a laboratory that is accredited through reciprocity has its certificate suspended or revoked by the other State or Federal agency, it shall notify the Department within 10 days of the suspension or revocation. The laboratory's certificate, issued by the Department, shall be suspended or revoked as of the effective date of the action taken by the other agency.

Note: Authority cited: Sections ~~208, 1011 and 1012~~***100275, 100830***, Health and Safety Code.
Reference: Sections ~~1011 and 1017~~***100825, 100860.1, 100865, 100870,*** , Health and Safety Code.

Article 13. Confidential Business Information

§64825. Confidential Business Information.

(a) If a laboratory identifies information provided to the Department as a trade secret or confidential business information, the Department shall not release such information unless:

(1) the release is authorized under state or federal law; and

(2) the Department has notified the laboratory of the impending release. Such notification shall be at least seven days prior to releasing any information identified as a trade secret, stating the name of the party requesting the information, the reason for the request, the authority to release this information, and the date the information will be released. The notification shall be faxed to the laboratory prior to sending through the mail.

(b) The laboratory shall clearly identify documents, laboratory functions, proprietary technical items, such as equipment, procedures, and other intellectual creations originated by the laboratory which fall under confidential business information. The form of identification shall be in writing and made available to the Department during the on-site inspections.

Note: Authority cited: Sections ***100275, and 100830***~~208, 1011 and 1012~~, Health and Safety Code.
Reference: ~~Sections~~ ***Section 100830***~~1012 and 1013~~, Health and Safety code; Section 6254.7(d), Government code.

Article 14. Sale or Transfer of Ownership of a Laboratory

§64827. Sale or Transfer of Ownership.

(a) A Laboratory will be required to cease testing and submit a new application if one or more of the following occurs.

(1) An original Owner and the new owner fails to notify the Department, in writing, within 15 days after a change in ownership.

(2) A new Owner relocates the laboratory within 90 days of assuming ownership.

(3) If more than half the number of laboratory persons either quit or are terminated and replaced by a new Owner within 90 days of assuming ownership.

(4) If a new Owner submits an application to alter the laboratory's certificate as issued to the prior Owner by the addition of analyte(s), group(s)-of-analytes, physical property, species, or method within any Field of Testing.

(b) A new Owner of a laboratory shall notify the Department, in writing, within 15 days after the sale or transfer of ownership and provide, at minimum, the following information.

(1) the name(s) of the new Owner(s);

(2) the date of sale or transfer of ownership;

(3) the name, education and laboratory related work experiences, as specified in Section 64817(a); or voluntary laboratory certificate grade as specified in Section 64817(b), of the designated director of the laboratory;

(4) the names, education and laboratory related work experiences, as specified in Section 64817.020(a) and (b); or voluntary laboratory certificate grade as specified in Section 64817.020(c), of all persons who are designated as supervisors;

(5) the names of all quality assurance officers, analysts, technicians, and assistants who have quit, or were terminated and replaced; and the names of all quality assurance officers, analysts, technicians, and assistants hired as replacements with education and laboratory related work experiences, as specified in Sections 64817.010, and 64817.030 through 064817.050;

(6) a statement that there will be no changes in laboratory location, or in the certificate issued to the prior Owner(s) within 90 days of assuming ownership;

(7) a statement that all equipment, method, and quality assurance practices will not change within 90 days of assuming ownership;

(8) a statement that the new owner will retain all records and data of analyses pursuant to Section 64816;

(9) applicable fees pursuant to Section 64806.030;

(10) the notice shall be signed by one or more of the new Owner(s).

(c) New Owners that comply with the provisions of (b) above shall have use of the certificate issued to the prior Owner for a period of ninety days commencing with the date of the Department's notice of receipt of the information supplied by the new Owner.

(1) The certificate number and the laboratory name appearing on the certificate shall remain the same until a new certificate is issued to the laboratory; and

(2) The new Owner shall display, and provide a copy with all data reports, the Department's notice recognizing the sale or transfer of ownership.

(d) The new Owners shall submit an application for a certificate, as specified in Section 64803 within 30 days from the date of the change of ownership. Within the 90-day-use period granted by the Department, the laboratory shall be in full compliance with Section 64803.010.

(e) Any records from the laboratory, which is subject to the change-of-ownership, shall become the responsibility of the new owner(s) to maintain pursuant to Section 64816.

(f) The Department shall be notified in writing by the laboratory owner(s) or delegated representatives of the owners and the laboratory directors of any change in ownership within 15

days, or directorship within 30 days. However, notice of change of ownership shall be the responsibility of both the current and new owners. Laboratory owners and directors, to whom the current certificate is issued, shall remain jointly and severally responsible to the Department for the operation, maintenance, and conduct of the laboratory and for any violations of Article 3 of the Health and Safety Code and these regulations including any failure to provide the notifications required by this section, until proper notice is received by the Department.

Note: Authority cited: Sections ***100275, 100825, 100830***~~208, 1011 and 1012~~, Health and Safety Code. Reference: Section ***100830 and 100845***~~1014~~, Health and Safety Code.

Article 16 . National Environmental Laboratory Accreditation Program Requirements.

§64859. NELAP Accreditation Process.

(a) Unless otherwise specified in this article, a laboratory applying for NELAP accreditation shall comply with the NELAC Standards as referenced in 100825 of the Health and Safety Code.

(b) A laboratory requesting a certificate of NELAP accreditation shall comply with Section 64803.010;

(c) A laboratory seeking to amendment its certificate shall comply with Section 64803.020;

(d) A laboratory requesting an interim certificate shall comply with Section 64803.030;

(e) A laboratory seeking to renew its certificate shall comply with Section 64803.040;

(f) A laboratory seeking reinstatement of its certificate after revocation shall comply with Section 64803.050;

(g) A laboratory seeking reinstatement of certification after suspension shall comply with Section 64803.060;

(h) Where there is mention of the Fields of Testing, Section 64885 and Section 100862 of the Health and Safety Code shall apply;

(i) Where there is mention of Field of Testing fees, Section 64860 shall apply.

Note: Authority cited: Sections 100275, 100830, 100840, and 100862, Health and Safety Code; and Section 15376, Government Code. Reference: Section 15376, Government Code; and Sections 100425, 100830, 100840, 100847, 100850, and 100851, Health and Safety Code.

§64860. NELAP Accreditation Fees.

(a) The following schedule of fees shall apply to every environmental laboratory applying for an initial, amendment, or renewal of a National Environmental Laboratory Accreditation Program (NELAP) primary or secondary accreditation:

(1) A non-refundable application fee of $3,000 payable at the time of initial and renewal application for accreditation, and

(2) An additional non-refundable fee for each Field of Testing specified in Health and Safety Code Section 100862 which the laboratory has requested in its application, payable at the time of application for an initial, amended, or renewed NELAP accreditation, as follows:

(A) A fee of $750 for each low complexity Field of Testing, identified as Fields of Testing number N115, N120, and N121.

(B) A fee of $1000 for each medium complexity Field of Testing, identified as Field of Testing number N101, N102, N103, N106, N107, N108, N109, N112, N114, and N118.

(C) A fee of $1,800 for each high complexity Field of Testing, identified as Field of Testing number N104, N105, N110, N111, N113, N116, N117 and N119.

(b) No environmental laboratory shall be approved as a NELAP accredited laboratory until fees provided by this section have been paid.

(c) The collected fees shall be placed in the ELIF fund solely for use in the certification of environmental testing laboratories.

Note: Authority cited: Sections 100830, 100835(a) and 100862, Health and Safety Code. Reference: Section 100825, Health and Safety Code.

§64860.010. Other Fees.

(a) For amendments to an existing certificate, the laboratory shall comply with Section 64806.010.

(b) For reinstatement to certification status, the laboratory shall comply with Section 64806.020 with the fees described in Section 64860.

Note: Authority cited: Sections 100275, 100830 and 100862, Health and Safety Code. Reference: Section 100825, Health and Safety Code.

§64862. Alternate Test Procedure & Method Modification Fees.

(a) A laboratory that submits an application for alternate test procedures (ATP) shall comply with Section 64806.030(b).

(b) A laboratory that submits an application for method modifications, which is not an ATP, shall comply with Section 64806.030(c).

Note: Authority cited: Sections 100275, 100830, 100840, and 100862, Health and Safety Code. Reference: Section 100825 and 100840, Health and Safety Code.

§64864. Fines.

(a) The owner(s) and director shall be jointly and severally responsible for violations as stated in Sections 64806.080. Such fines shall be paid in addition to application fees that appear in Section 64860.

(b) The laboratory shall also be subject to citations and fines for violations described in Section 64806.100.

Note: Authority cited: Sections 100275, 100830, and 100880, Health and Safety Code. Reference: Section 100880, Health and Safety Code.

§64870. Application Process.

(a) A laboratory seeking NELAP accreditation in any Field of Testing identified in Section 64885 as listed in Health and Safety Code Section 100862 shall comply with Section 64803 and file a complete application utilizing ELAP101 rev01.

Note: Authority cited: Sections 100275, 100825, 100830, 100840, and 100862, Health and Safety Code. Reference: Section 100825, Health and Safety Code.

§64885. Fields of Testing.

(a) The laboratory shall provide to the Department the desired Fields of Testing from H&SC 100862(a) and include the analyte, group-of-analytes, physical property, or species along with the method for which the certificate is to be issued.

(b) The laboratory shall use only the method which appears on its certificate and which is applicable for the detection and/or the quantitation of the analyte, group-of-analytes, or physical property. The method shall be Federal or State approved for testing of environmental samples for the desired Field of Testing.

(c) Laboratories, certified for the Fields of Testing involving drinking water and requesting use of alternate test procedures (ATP) for Federal regulated analytes group-of-analytes or physical properties, shall be in compliance with the Code of Federal Regulations, July 1, 2006, title 40, part 141.27, and shall be in possession of a document from the U.S. Environmental Protection Agency that shows approval for use of the procedures, prior to their use on environmental samples. Laboratories testing for analytes, group-of-analytes, or physical properties that are not Federal regulated but are monitored by the State, shall comply with Section 64811.0100.

(d) Laboratories, certified for Fields of Testing involving wastewater and requesting use of alternate test procedures (ATP) for Federal regulated analytes, group-of-analytes, physical properties, or species, shall be in compliance with the Code of Federal Regulations, July 1, 2006, title 40, part 136.4, and shall be in possession of a document from the U.S. Environmental Protection Agency that shows approval for use of the procedures, prior to their use on environmental samples. Laboratories testing for analytes, or group-of-analytes, physical properties, or with species that are not Federal regulated but are monitored by the State, shall utilize methods approved by the State.

(e) Laboratories, certified for hazardous waste Fields of Testing and requesting use of alternate test procedures (ATP) for Federal or State regulated analytes, group-of-analytes, physical properties, or species shall be in compliance with the California Code of Regulations, Title 22, sections 66260.21(a) and 66260.21(b), and shall have been granted a variance by the California State Department of Toxic Substances Control, Environmental Chemistry Laboratory (ECL), formerly the Hazardous Materials Laboratory (HML), for the procedures prior to their use on environmental samples.

(f) For Proposition 65, each laboratory shall comply with requirements set by the Office of Environmental Health Hazard Assessment (OEHHA). For each analyte, group-of-analytes, or physical property affected by Proposition 65, the laboratory shall perform applicable analyses based on its certificate and applicable Field of Testing for the matrix of the sample.

(g) A certified laboratory, planning to modify a method in an area that is not allowed by the method for modification and where the modification is not an ATP, shall comply with the process for performance based methods described in the California State Quality Manual for Environmental Testing Laboratories of Section 64815.010, unless otherwise described in the NELAC Standards of Section 100825 of the Health and Safety Code.

(h) A laboratory, certified for Fields of Testing involving drinking water, wastewater, or ambient waters, shall not use performance based methods, unless otherwise stated in the Code of Federal Regulations (title 40, parts 136 and 141) by the U.S. Environmental Protection Agency.

(i) A certified laboratory, planning to make modifications within a Federal or State approved method where such modifications are allowed as stated in the method, shall follow the process for method modifications described in the California State Quality Manual for Environmental Testing Laboratories of Section 64815.010.

Note: Authority cited: Section 100275, 100825, and 100830, Health and Safety Code. Reference: Sections 100830 and 100862 Health and Safety Code; Section 12901, Title 22, California code of Regulations; Appendices I, II and III of Article 5 (commencing with Section 66261.100), Title 22, California Code of Regulations.